



AP/3721/A

TRANSMITTAL OF APPEAL BRIEF (Small Entity)

Docket No.
STEU-3250

Re Application Of: Thomas D. Taggart

Serial No.	Filing Date	Examiner	Group Art Unit
09/871,078	05/31/2001	Tawfik, S.	3721

Invention: **METHOD AND APPARATUS FOR ASEPTIC PACKAGING**

TO THE ASSISTANT COMMISSIONER FOR PATENTS:

Transmitted herewith in triplicate is the Appeal Brief in this application, with respect to the Notice of Appeal filed on:

Applicant is a small entity under 37 CFR 1.9 and 1.27.

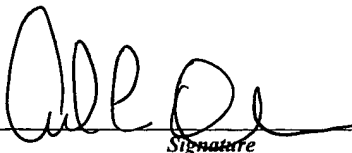
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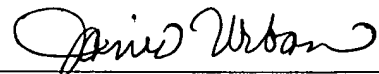
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Dated: October 16, 2002

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant: Taggart) Examiner: Tawfik, S.
Serial No.: 09/871,078) Art Unit: 3721
Filed: 05/31/01)

Title: **METHOD AND APPARATUS FOR ASEPTIC PACKAGING**

Commissioner for Patents
Washington, D.C. 20231

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BRIEF OF APPELLANTS

Sir:

This Appeal Brief, pursuant to the Notice of Appeal filed August 20, 2002 in the above identified application, is an appeal from the final rejection of May 20, 2002.

REAL PARTY IN INTEREST

Steuben Foods, Incorporated is the real party in interest.

RELATED APPEALS AND INTERFERENCES

A related appeal is Appeal No. 2002-1063 for application 09/306,552. The instant application, 09/871,078, is a divisional of application 09/306,552.

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STATUS OF CLAIMS

Claims 20, 22 and 35-62 are currently pending. They are set forth in the Appendix. Claims 23-34 have been withdrawn from consideration. This Brief is in support of an appeal from the rejection of claims 20, 22 and 35-62.

STATUS OF AMENDMENTS

The IDS submitted on June 25, 2002 was considered on July 23, 2002 and entered. The Request for Reconsideration, dated July 9, 2002, was considered on August 1, 2002 and was indicated as being entered for purposes of Appeal.

SUMMARY OF INVENTION

The present invention relates to a method and device for automatically aseptically bottling aseptically sterilized foodstuffs. In general, the two independent claims, 20 and 22, relate to aseptically disinfecting bottles at a rate greater than 100 bottles per minute *and* aseptically filling the bottles with aseptically sterilized foodstuffs. Specifically, claim 20 on appeal is directed to a method for automatically aseptically bottling aseptically sterilized foodstuffs comprising the steps of: providing a plurality of bottles; aseptically disinfecting the plurality of bottles at a rate greater than 100 bottles per minute; and, aseptically filling the bottles with aseptically sterilized foodstuffs. Claim 22 on appeal is directed to a device for automatically aseptically bottling aseptically sterilized foodstuffs comprising the steps of: means for providing a plurality of bottles; means for aseptically disinfecting the plurality of bottles at a rate greater than 100 bottles per minute; and, means for aseptically filling the bottles with aseptically sterilized foodstuffs.

The invention meets the various United States FDA aseptic standards and the 3A Sanitary Standards and Accepted Practices (page 9, lines 7-10). The term “aseptic” as used in the invention denotes the United States FDA level of aseptic (page 9, line 11).

ISSUES

1. Whether claims 20 and 35-47 are not unpatentable under 35 U.S.C. §103(a) over Gies (United States Patent 4,862,933) in view of Olsson (United States Patent 5,799,464).
2. Whether claims 22, 48-55 and 57-62 are not unpatentable under 35 U.S.C. §103(a) over Gies (United States Patent 4,862,933) in view of Olsson (United States Patent 5,799,464).
3. Whether claim 56 is not unpatentable under 35 U.S.C. §103(a) over Gies (United States Patent 4,862,933) in view of Olsson (United States Patent 5,799,464) and further in view of Poole (United States Patent 2,491,015).

GROUPING OF CLAIMS

- I. Claims 20 and 35-47 stand or fall together;
- II. Claims 22, 48-55 and 57-62 stand or fall together; and
- III. Claim 56 stands or falls alone.

ARGUMENT

Appellant respectfully submits that the rejections based on various combinations of Gies, Olsson, and Poole are defective because these references, taken alone, or in combination, fail to teach or suggest each and every feature of the claims as required by 35 U.S.C. §103. Further,

Appellant respectfully submits that the Examiner has failed to present a *prima facie* case of obviousness in support of the rejection under 35 U.S.C. §103.

Briefly, the three patents cited by the Examiner for rejection of the claims are as follows: Gies discloses a doser for sterilant in a packaging system. Olsson discloses a method for aseptic and automatic transfer of unsealed pharmaceutical containers. Poole discloses a method for sterilizing wooden produce baskets.

Issue 1

CLAIMS 20 AND 35-47 ARE NOT UNPATENTABLE UNDER 35 U.S.C. §103(a) OVER GIES (U.S. PATENT 4,862,933) IN VIEW OF OLSSON (U.S. PATENT 5,799,464).

In order for the Examiner to reject the claimed invention he must identically disclose each and every feature of the claimed invention as set forth in 35 USC 102 or obviate the same as set forth in 35 USC 103. It is appellant's position that the Examiner has not met this burden. In particular, the prior art cited in the Final Office Action, dated May 20, 2002, does not teach, suggest or obviate each and every feature of independent claim 20.

The Examiner on page 2 of the Final Office Action states that:

Gies discloses a method and apparatus for aseptically packaging aseptically sterilized foodstuffs comprising the means for providing a plurality of containers (cups 15); aseptically disinfecting the plurality of containers (apparatus 19) see for example (column 4, lines 18-23); aseptically filling the aseptically disinfected plurality of containers with the foodstuffs (apparatus 20) see for example (column 4, lines 23-25); and aseptically disinfected plurality of containers at a rate greater than 100 container per minute (column 4, lines 35 and 36) the machine can be operated to produce 33,600 packages per hour which is equal to 560 packages per minute.

Furthermore, the Examiner states:

Applicant argue in page 6 of the argument that Gies's reference does not teach aseptic

operation, only teaches pre-sterilization of containers. The examiner believes that Gies as modified by involving of routine skill in the art will be able to sterilize the food product to a level at least 12 log and the container to a level at least 6 log as the applicant claimed, that will be considered aseptic. See Final Office action Page 5, lines 14-18.

The Examiner further alleges that Gies teaches all of the elements of claims 20, 22, 35-55 and 57-62, with the exception of disclosing “the container is bottle made of plastic or glass” (sic), page 2 of Final Office Action. The Examiner further alleges that Olsson teaches the aforementioned containers that are bottles, such that Olsson may be combined with Gies for rejecting the aforementioned claims by way of obviousness. Respectfully, Appellant disagrees. Appellant provides the following six reasons why the Examiner has not established a *prima facie* case of obviousness in relation to independent claim 20.

First, the Examiner has not established a *prima facie* case of obviousness in relation to claim 20 in that Gies and Olsson, whether taken alone or in combination, do not teach, suggest, or obviate the claimed invention. Specifically, the combination does not disclose or obviate “filling the bottles with aseptically sterilized foodstuffs”, as recited in claim 20. There is no disclosure of aseptically sterilized foodstuffs in Gies. In order to meet the aseptic FDA standard, *inter alia*, a “Ultra High Temperature” (UHT) pasteurization process is required for the foodstuff preparation (Page 24, lines 14-19). Yet, in Gies, there is no teaching or disclosure of any heating of the food product prior to placement in the cups. Olsson does not overcome these glaring deficiencies in Gies. Based on the preceding argument, in light of both Gies and Olsson, the PTO cannot utilize Gies to support an obviousness rejection of claim 20.

A second reason why the Examiner has not established a *prima facie* case of obviousness in relation to claim 20 is that Gies does not disclose or obviate an “aseptic” sterility process

anywhere in the patent. There is no specific level of sterility disclosed in Gies. Although “sterile” and “sterilizer” and the like are used throughout the Gies’ specification, nowhere is a specific, measured level of sterilization used. Referring to Appellant’s specification, the food industry has different standards and requirements that must be met when using the term “aseptic”. By way of example, the term “Extended Shelf Life” (ESL) may be used when the packaging material is sanitized and filled with a product in a pre-sterilized tunnel under “ultra-clean” conditions. Using ESL packaging, the product life is extended from about 10-15 days to about 90 days. See pg. 2, lines 3-10 of the specification. In contrast, “aseptic” packaging has a shelf-life of 150 days or more. See page 2, lines 10-14 of the specification. The only disclosure of any sort related to filling sterilization magnitude is in the Background of the Invention section of Gies (Col. 1, lines 15-17) wherein it states “[t]he filling and sealing are done under substantially sterile conditions” (emphasis ours). “Substantially sterile” and “aseptic” are clearly not synonymous to an artisan of ordinary skill in the food industry. Further, this difference is highly significant, for without meeting the FDA definition of aseptic, as the present invention does, the resulting packaged product *inter alia* will not be able to be labeled “aseptic”. By attaining the FDA standards for “aseptic”, as the present invention does, there are a myriad of significant, critical items that are bestowed upon the products, including *inter alia*: being able to label products as “aseptic”; significantly longer products shelf lives (e.g., 150+ days for aseptic packaging vs. c. 90 days for ESL packaging, Page 2, lines 11-15), non-refrigeration of products, and other important features. This difference in sterilization levels is one of kind, not just one of degree. Based on the preceding argument, the PTO cannot utilize Gies to support an obviousness rejection of claim 20.

A third reason why the Examiner has not established a *prima facie* case of obviousness in relation to claim 20 is that the levels of sterilization in the present invention are not within, nor touch, the range previously disclosed in Gies. As stated above, the levels of sterilization taught in Gies are only “substantially sterile” in the filling and sealing steps (Col. 1, lines 15-17). Contrastingly, in the present invention, the bottles are *aseptically* disinfected; the bottles are *aseptically* filled; *and*, the bottles are filled with *aseptically* sterilized foodstuffs. Clearly, the sterilization level of “aseptic”, for disinfecting bottles, for filling bottles, *and* for sterilizing the foodstuffs, is much greater than just filling and sealing cups at a “substantially sterile” level.

The case of *In re Geisler*, 43 USPQ.2d 1362 (Fed. Cir. 1997), illustrates why the Examiner has not shown a *prima facie* case of obviousness in that the ranges of sterilization of the present invention do not overlap or touch with the prior art. In *Geisler* the *prima facie* case of obviousness under 103 was affirmed. *Geisler* involved claims related to a protective layer for a reflective article wherein the thickness of the layer in the claimed article *overlapped with ranges of thickness disclosed in the prior art*. Ultimately, the Court in *Geisler* relied, in part, on applying the *Malagari* test (*In re Malagari*, 499 F.2d 1297, 1303, 182 USPQ 549, 553 (CCPA 1974)), wherein a claimed invention is rendered *prima facie* obvious by the teachings of a prior art reference that discloses a *range that touches the range recited in the claim* (emphasis ours). Thus, in the present invention, the *Malagari* test fails because there is no overlapping or touching of ranges of sterilization. An entirely aseptic process resulting in an aseptically process and packaged food product does not overlap with Gies which only speaks to a process that produces a “substantially sterile” product. *Geisler* further shows how there is no case of *prima facie* obviousness. Based on the preceding argument, in light of *In re Geisler* and the *Malagari* test,

the PTO cannot utilize Gies to support an obviousness rejection of claim 20.

A fourth reason why the Examiner has not established a *prima facie* case of obviousness in relation to claim 20 is that the levels of sterilization in the present invention do not, as the Examiner alleges, take only routine skill to modify Gies so as to reach the aseptic levels of sterilization, as in the present invention. Both in the Response to Arguments section of the Final Office Action and in the rejection of several claims, the Examiner uses *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) for the premise that discovering an optimum value of a result effective variable involves only routine skill in the art. Respectfully, *In re Boesch* core teaching is that the discovery of an optimum value of the variable takes only routine skill (emphasis ours). To the contrary, the present invention does not claim “discovery” of a value, but rather discloses “reaching” or “obtaining” several values (i.e., sterilization level and speed). *Boesch* details a case wherein the Court rejected as obvious a claimed alloy with an average number of electron vacancies to not exceed 2.35. The prior art in *Boesch* disclosed alloys with the same compositional limits (See *Boesch* at 218) as the claimed invention. Thus, the final rejection was rightfully based on this premise that finding the best proportion of ingredients for these alloys takes only routine skill. Now, the present invention does not involve proportions, ingredients, percentages, or the like. The present invention involves the ability to obtain new levels of sterility thereby allowing wholly different shelf lives and storage requirements (i.e., refrigeration versus non-refrigeration; up to one year or more shelf life versus weeks or months) and of sterilizing speed for bottles that together have never heretofore been obtained. Simply put, no one prior to this invention has been able to aseptically disinfect bottles at a rate close to 100 bottles per minute and aseptically fill them with aseptic foodstuffs. Obtaining these landmarks

takes much more than routine skill in the art. Based on the preceding argument, in light of *In re Boesch*, the PTO cannot utilize Gies to support an obviousness rejection of claim 20.

A fifth reason why the Examiner has not established a *prima facie* case of obviousness in relation to claim 20 is that the combination of Olsson and Gies is improper hindsight. The Examiner looked to Olsson for the premise of using bottles, in lieu of cups in Gies. Olsson teaches a method and device for aseptic and automatic transfer of *unsealed* pharmaceutical containers (Col. 1, lines 5-7). Olsson, in other words, takes filled, yet unsealed, pharmaceutical containers and then maintains their sterility by using a device and method so that the containers then can be transferred to a subsequent station for additional processing of the product in the containers, such as a freeze-drying step. Gies, conversely, discloses *inter alia* a packaging system that doses sterilant at a sterilizing apparatus 19 and then, immediately subsequent, fills the cups with product at a filling machine 20, and then, immediately subsequent, places a cover disk and seals the cups by machines 21 and 22, respectively. Gies, in short, is a continuous, closely arranged system (see in general Fig. 1). There would be no motivation for one to modify Gies and to look to Olsson. There would be no reason to look to interrupt the continual packaging flow of Gies with a device, such as in Olsson, that takes containers from one processing step and moves the containers slowly to another distant processing step. This is improper hindsight analysis of the claimed invention by the Examiner. Based on the preceding argument, in light of both Gies and Olsson, the PTO cannot utilize Gies to support an obviousness rejection of claim 20.

A sixth reason why the Examiner has not established a *prima facie* case of obviousness in relation to claim 20 is that by combining Olsson with Gies would destroy a purpose of the

Gies invention. As mentioned above, Olsson teaches the aseptic transfer of unsealed containers in a device. Gies *inter alia* produces 33,600 packages per hour (Col. 4, lines 35-36). Were one to combine the device/method in Olsson, clearly, the packaging rate in Gies would be completely destroyed, and thus unobtainable. Based on the preceding argument, in light of both Gies and Olsson, the PTO cannot utilize Gies to support an obviousness rejection of claim 20.

Based on the aforementioned arguments, independent claim 20, and dependent claims 35-47, which depend on claim 20 are in condition for allowance.

Issue 2

CLAIMS 22, 48-55, and 57-62 ARE NOT UNPATENTABLE UNDER 35 U.S.C. §103(a) OVER GIES (U.S. PATENT 4,862,933) IN VIEW OF OLSSON (U.S. PATENT 5,799,464).

The Examiner has not established a *prima facie* case of obviousness in relation to independent claim 22 in that Gies and Olsson, whether taken alone or in combination, do not obviate the claimed invention. Clearly, the limitations in claim 22 invoke 35 U.S.C. 112, sixth paragraph. The three limitations in claim 22: “means for providing a plurality of bottles”; “means for aseptically disinfecting the bottles at a rate greater than 100 bottles per minute”; and, “means for aseptically filling the bottles with aseptically sterilized foodstuffs”, all meet the requisite 3-prong test for invocation of 35 U.S.C. 112, sixth paragraph. First, all three limitations use the phrase “means for”. Second, all three limitations have functional language modifying “means for” (i.e., “providing”, “aseptically disinfecting”, and “aseptically filling”). Third, none of the “means for” limitations in claim 22 are modified by structure, material or acts for achieving their respective functions.

First, unless an element performs the identical function specified in the claim, it cannot be an equivalent for purposes of 35 U.S.C. 112, sixth paragraph. *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 4 USPQ2d 1737 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 961 (1988). Clearly, several of the elements of the Gies Olsson combination do not perform identical functions as those specified in claim 22. First, the Gies Olsson combination does *not* perform identically to the element: **“means for aseptically disinfecting bottles”**, as recited in claim 22. In order for aseptic packaging to occur, it must meet the FDA definition of “aseptic” the aseptic filler must, *inter alia*, “use an FDA approved sterilant, meet FDA quality control standards, use a sterile tunnel or clean room, and must aseptically treat all packaging material.” Page 2, lines 18-22. Also, “packaging material must remain in a sterile environment during filling, closure, and sealing operations.” Page 2, lines 24-26. Included in the “means for aseptically disinfecting bottles”, the present invention applies hot atomized sterilant onto the interior surface of each container and subsequently activates and removes the sterilant using hot sterile air (Page 5, lines 18-21). This is done, in part, by the extension of applicator spray nozzles 122 into the interior of the bottles (Page 19, lines 12-20). Further, the bottles are then heated for a predetermined period of time after application of sterilant. Hot sterile air is delivered at a high volume and a relatively low temperature to dry the bottle (Page 5, line 23 - page 6, line 3). Conversely, Gies does not teach or suggest *several* of the elements required to provide the “means for aseptically disinfecting bottles”. Gies does not teach or suggest meeting FDA quality control standards. Gies does not teach or suggest using a sterile tunnel or clean room in its packaging. Gies does not teach or suggest aseptically treating all the packaging material. Further, Gies does not teach or suggest heating or atomizing the sterilant prior to applying it. Gies does not teach or suggest

extending an applicator nozzle into a bottle interior. Gies does not teach or suggest heating or applying hot sterile air to the bottles, after application of sterilant and thus, does not perform this function. Olsson does not overcome all these glaring deficiencies in Gies. Based on the preceding argument, in light of both Gies and Olsson, the PTO cannot utilize Gies to support an obviousness rejection of claim 22.

Additionally, the combination does not perform the identical function of **“means for aseptically filling the bottles”**, as recited in claim 22, and thus, cannot be an equivalent for purposes of 35 U.S.C. 112, sixth paragraph. As stated above, in order to meet the FDA definition of “aseptic” the aseptic filler must, *inter alia*, “use an FDA approved sterilant, meet FDA quality control standards, use a sterile tunnel or clean room, and must aseptically treat all packaging material.” Page 2, lines 18-22. Clearly, Gies does not teach or suggest the use of a sterile tunnel or clean room during the filling of the bottles, as is required to meet the FDA standards for aseptic, proving once again that the Gies’ “substantially sterile” process is completely, and critically, different from the process disclosed in the matter on appeal. Contrastingly, Gies only discloses filling and sealing that are done under “substantially sterile conditions” (Col. 1, line 16). Clearly, “substantially sterile conditions” and “aseptic” are not synonymous. This is a difference of kind, and not of degree. Olsson does not overcome these glaring deficiencies in Gies. Based on the preceding argument, the PTO cannot utilize Gies and Olsson to support an obviousness rejection of claim 22 because the combination does not perform identical function specified in the claim.

Further, there are several indicia that further support the conclusion that the combination of Gies and Olsson is not equivalent prior art that performs the claimed function and thus, cannot

be used to support an obviousness rejection under 35 U.S.C. 103.

First, the Gies and Olsson combination does not perform the identical function in substantially the same way as the claimed invention. *Kemco Sales, Inc. v. Control Papers Co.*, 208 F.3d 1352, 54 USPQ2d 1308 (Fed. Cir. 2000). *See also Graver Tank & Mfg. Co. v. Linde Air Products*, 339 U.S. 605, 85 USPQ 328 (1950). Gies does not “aseptically disinfect the bottles”. Nor does Gies “aseptically filling the bottles”, as recited in claim 22. Finally, Gies does not disinfect the bottles “at a rate great than 100 bottles per minute” and does not aseptically fill the bottles “with aseptically sterilized foodstuffs”. Gies not only does not perform these identical functions, Gies also does *not* do them in substantially the same way as in claim 22. As discussed in the aforementioned argument, there are several elements omitted from Gies (e.g., sterile tunnel, heating sterilant, aseptically treating packaging, extending applicator nozzle into bottle interior, applying hot sterile air to bottles after applying sterilant, etc.). The logical conclusion must be that Gies, along with Olsson, does perform functions in substantially the same way as the claimed invention.

Second, Gies and Olsson do not produce substantially the same results as the corresponding element disclosed in the specification. *Kemco Sales, Inc. v. Control Papers Co.*, 208 F.3d 1352, 54 USPQ2d 1308 (Fed. Cir. 2000). As discussed above, Gies and Olsson do not produce an element which can “aseptically disinfect the bottles at a rate greater than 100 bottles per minute”. Further, Gies and Olsson do not produce an element which can “aseptically filling the bottles with aseptically sterilized foodstuffs”. “[F]illing and sealing are done under substantially sterile condition” (Col. 1, lines 15-16) is simply not substantially the same result as meeting the full FDA requirements for “aseptic” processing. This is a distinction with a

difference, not an obvious improvement.

Third, a person of ordinary skill would not recognize the interchangeability of the elements in Gies and Olsson for the corresponding element disclosed in the specification.

Caterpillar Inc. v. Deere & Co., 224 F.3d 1374, 56 USPQ2d 1305 (Fed. Cir. 2000). There are too many elements omitted (e.g., sterile tunnel, hot air nozzle, extending applicator nozzle, heater for sterilant, etc.) from Gies and Olsson to suggest that one of ordinary skill would recognize any interchangeability with the claimed invention.

Fourth, there are substantial differences between Gies and Olsson and corresponding elements disclosed in the specification. *IMS Technology, Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1436, 54 USPQ2d 1129, 1138 (Fed. Cir. 2000). As discussed above, there are several substantial differences between Gies and Olsson and the corresponding elements in the specification. By way of example, the specification discloses a sterile tunnel; Gies and Olsson disclose none. The specification discloses a sterilant applicator nozzle which extends into the interior of the bottle; Gies and Olsson discloses an apparatus 19 that applies sterilant to a cup. There is no teaching, or suggestion, of extending the applicator *within* a bottle. There is no teaching, or suggestion, of heating the sterilant subsequent to its application, as is disclosed in the present invention. Further, the present invention discloses applying hot air to the bottles; there is no suggestion of this in Gies, or Olsson. Several of these differences allow, in part, for the present invention to meet the FDA definition of “aseptic”. In sum, there are several substantial differences between corresponding elements between Gies and Olsson and the present invention.

Fifth, elements in the Gies/Olsson combination are not the structural equivalent of corresponding elements disclosed in the specification. *In re Bond*, 910 F.2d 831, 15 USPQ2d

1566 (Fed. Cir. 1990). As much of the aforementioned discussion makes clear, there are simply so many elements that are missing from the Gies/Olsson combination that they cannot be the structural equivalent of all the corresponding elements disclosed in the specification.

Based on the aforementioned arguments, independent claim 22, and dependent claims 48-44, and 57-62, which depend on claim 22 are in condition for allowance.

Issue 3

CLAIM 56 IS NOT UNPATENTABLE UNDER 35 U.S.C. §103(a) OVER GIES (U.S. PATENT 4,862,933) IN VIEW OF OLSSON (U.S. PATENT 5,799,464) AND FURTHER IN VIEW OF POOLE (U.S. PATENT 2,491,015).

The prior art cited in the Final Office Action does not teach each and every feature of claim 56. Specifically, neither Gies, Olsson, or Poole, individually or in combination, teach or suggest “means for aseptically disinfecting the bottles includes disinfecting **an outside surfaces of the bottles** with hydrogen peroxide”.

The Examiner alleges that Gies in view of Olsson teaches all of the elements of claim 56, except disclosing “disinfecting the container from the outside surfaces.” The Examiner further alleges that Poole teaches the aforementioned disinfecting of the outside surfaces of the bottles, such that Poole may be combined with Gies and Olsson for rejected claim 56 by way of obviousness. Appellant provides the following two reasons why the Examiner has not established a *prima facie* case of obviousness in relation to claim 56.

A first reason why the Examiner has not established a *prima facie* case of obviousness in relation to claim 56 is that if a complete container immersion in sterilant of Poole was used in

Gies, the container immersion would destroy a purpose of the Gies invention. In *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984), the Federal Circuit reversed the PTO's rejection of the claimed invention. The claimed invention was a blood-filter assembly used during surgery. The PTO rejected the claimed invention for obviousness based on the reference of French (U.S. Patent 1,175,948), which taught a filter-separator assembly that would have to be turned upside down in order to teach the elements of the claimed invention. See *In re Gordon*, 221 USPQ at 112y. In reversing the PTO, the Federal Circuit reasoned that turning the French filter-separator upside down would not allow the French apparatus to perform its filtration-separation functionality and therefore cannot be used to support a *prima facie* case of obviousness. See *In re Gordon*, 221 USPQ at 1127.

Appellant contends that the Examiner's application of Poole with Olsson and Gies to claim 56 is in accordance with the Federal Circuit's analysis of *In re Gordon*, because the full container immersion in Poole would not allow the Gies patent to satisfy its objective of "delivering a [sterilizing] liquid in exact doses." Gies, col. 1, lines 6-7. It is clear in Gies, that the application of a highly accurate amount of sterilant is of paramount importance to the patent. See the Background of the Invention e.g., Col. 1, lines 41-45 "it is *essential* that the amount [of sterilant] used be *very accurately* dosed. If too little sterilizing liquid is used the product in the unsterilize package will spoil; if *too much* is used the product will be flooded and diluted. Either way the product will be *ruined*" (emphasis ours). See Col. 5, lines 8-9 "exactly the same quantity of [sterilizing] liquid will be dosed." Finally, see Col. 5, lines 47-50 "[t]he construction of the device makes the opposite problem - overfeed to *flood* the objects being sterilized - virtually impossible." Contrastingly, Poole discloses throughout specification, claims and figures of a full

immersion in a liquid bath of sterilant. Clearly, Poole's full immersion would simply destroy the primary purpose of Gies in applying highly accurate doses of sterilant to the inside of a cup. Based on the preceding argument, in light of *In re Gordon*, the PTO cannot utilize Poole to support an obviousness rejection of claim 56.

A second reason the Examiner has not established a *prima facie* case of obviousness in relation to claim 56 is that the use of *In re Leshin*, 125 USPQ 416, by the Examiner is incorrect. Specifically, the Examiner used the *Leshin* case for the premise that it is an obvious design choice to select a known material (i.e., bottle) on the basis of its suitability for the intended use. In other words, *Leshin* justifies the premise to combine Poole with the Gies/Olsson combination. *In re Leshin* involved a obviousness rejection of claims for a lipstick container made out of known plastics. In the present invention however, the sterilization of a *bottle* is not an obvious material substitution for a cup. As is discussed throughout the specification, although the sterilization of the *material* the bottle is made out of is important, it is in large part the *configuration, geometry, and shape* of the bottle (vs. a cup) that makes aseptic sterilization so difficult, and thus critical. See, for example, page 5, lines 4-16:

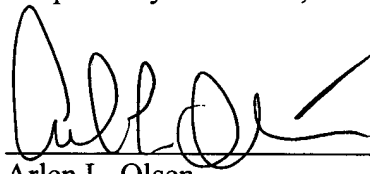
The interior surface of a container such as a bottle or jar is much more difficult to aseptically sterilize than the interior surface of a cup. A cup generally has a large opening compared to its height, whereas a bottle or jar generally has a small opening compared to its height and its greatest width (e.g., the ratio of the opening diameter to the height of the container is less than 1.0). A sterilant can be introduced, activated, and removed in a cup much more rapidly than in a bottle or jar. The processing speed when using a bottle or jar is limited, in part, by the time required to aseptically sterilize the interior surface of the bottle or jar. The aseptic processing apparatus of the present invention overcomes the processing speed limitations associated with the use of containers such as bottles or jars.

Based on the preceding argument, the PTO cannot utilize Poole to support an obviousness rejection of claim 56.

For the preceding reasons, Applicant maintains that claim 56 is not obvious and thus cannot be rejected over Gies in view of Olsson and further in view of Poole under U.S.C. §103(a). Accordingly, Applicant maintains that claim 56 is in condition for allowance.

In summary, Applicant respectfully requests reversal of the U.S.C. §103(a) rejections of claims 20, 22, 35-62.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'A. Olsen', is written over a horizontal line.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant: Taggart)	Examiner: Tawfik, S.
)	
Serial No.: 09/871,078)	Art Unit: 3721
)	
Filed: 05/31/01)	

Title: **METHOD AND APPARATUS FOR ASEPTIC PACKAGING**

APPENDIX - CLAIMS ON APPEAL

20. A method for automatically aseptically bottling aseptically sterilized foodstuffs comprising the steps of:

- providing a plurality of bottles;
- aseptically disinfecting the bottles at a rate greater than 100 bottles per minute; and
- aseptically filling the bottles with aseptically sterilized foodstuffs.

22. A device for automatically aseptically bottling aseptically sterilized foodstuffs comprising:

- means for providing a plurality of bottles;
- means for aseptically disinfecting the bottles at a rate greater than 100 bottles per minute;

and

- means for aseptically filling the bottles with aseptically sterilized foodstuffs.

35. The method according to claim 20, wherein the plurality of bottles are made from a glass.

36. The method according to claim 20, wherein the plurality of bottles are made from a plastic.

37. The method according to claim 36, wherein the plastic is selected from the group: polyethyleneterephthalate, and high density polyethylene.

38. The method according to claim 20, wherein the aseptic filling is at a rate greater than 100 bottles per minute.
39. The method according to claim 20, further including capping the bottle with a aseptically disinfected lid.
40. The method according to claim 20, wherein the disinfecting the bottles is with hot hydrogen peroxide spray.
41. The method according to claim 40, wherein the aseptically disinfecting the bottles includes an application of the hot hydrogen peroxide spray for about 1 second into an interior of the bottle and an activation and removal of the hot hydrogen peroxide using hot aseptically sterilized air for about 24 seconds.
42. The method according to claim 20, further including a feedback control system for maintaining aseptic bottling conditions.
43. The method according to claim 40, wherein the aseptically disinfecting the bottles includes an application of the hot hydrogen peroxide spray for about 1 second onto an outside surface of the bottle and an activation and removal of the hot hydrogen peroxide using hot aseptically sterilized air for about 24 seconds.
44. The method according to claim 20, wherein the step of aseptically filling the bottles further comprises: filling the aseptically disinfected bottling at a rate greater than 360 bottles per minute.
45. The method according to claim 20, wherein the aseptically sterilized foodstuffs are sterilized to a level producing at least a 12 log reduction in *Clostridium botulinum*.
46. The method according to claim 20, wherein the aseptically disinfected plurality of bottles are

sterilized to a level producing at least a 6 log reduction in spore organisms.

47. The method according to claim 40, wherein a residual level of hydrogen peroxide is less than .5 PPM.

48. The device according to claim 22, wherein each bottle has an opening size to height ratio of less than one.

49. The device according to claim 22, wherein the plurality of bottles are made from a glass.

50. The device according to claim 22, wherein the plurality of bottles are made from a plastic.

51. The device according to claim 50, wherein the plastic is selected from the group: polyethylene terephthalate and high density polyethylene.

52. The device according to claim 22, wherein the means for aseptically disinfecting the bottles further includes means for disinfecting an interior of the bottles with a hot hydrogen peroxide spray.

53. The device according to claim 52, wherein the means for disinfecting an interior of the bottles includes an application of the hot hydrogen peroxide spray for about 1 second and an activation and removal of the hot hydrogen peroxide using hot aseptically sterilized air for about 24 seconds.

54. The device according to claim 22, further including means for feedback control for maintaining aseptic bottling conditions.

55. The device according to claim 22, wherein means for aseptically disinfecting is provided by one of the group: hydrogen peroxide and oxonia.

56. The device according to claim 22, wherein means for aseptically disinfecting the bottles includes disinfecting an outside surfaces of the bottles with hydrogen peroxide.

57. The device according to claim 56, wherein the disinfecting the outside surfaces includes about 1 second for the application of the hot hydrogen peroxide spray and about 24 seconds for an activation and removal of the hot hydrogen peroxide using hot aseptically sterilized air.

58. The device according to claim 22, wherein the means for aseptically disinfecting the bottles further comprises: aseptically disinfecting the bottles at a rate greater than 360 bottles per minute.

59. The device according to claim 22, wherein the means for aseptically filling the bottles further comprises: aseptically filling the bottles at a rate greater than 100 bottles per minute.

60. The device according to claim 22, wherein the aseptically sterilized foodstuffs are sterilized at a level producing at least a 12 log reduction in *Clostridium botulinum*.

61. The device according to claim 22, wherein the aseptically disinfected bottles are sterilized to a level producing at least a 6 log reduction in spore organisms.

62. The device according to claim 53, wherein the residual level of hydrogen peroxide is less than .5 PPM.